REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested. Claims 1-24 are pending in the application, with claim 1 being the sole independent claim. Claims 3, 6-8, 11, and 12 are withdrawn from consideration as being drawn to a nonelected species pending allowance of generic claim 1.

35 U.S.C. § 103(a)Rejections

Claims 1, 2, 4, 5, 9, 10, 13, 15, 16, 18-20, 22 and 23 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,304,121 to Sahatjian in view of U.S. Patent No. 5,760,200 to Miller *et al.* The Examiner states that Sahatjian discloses "a delivery catheter, a stent framework and a porous material with a salt of a therapeutic material (see figs. 4-6 and col. 9 lines 21-34)." Office Action p. 2. The Examiner acknowledges that Sahatjian does not disclose using a water insoluble salt as a therapeutic material. *Id.* at 3. The Examiner states that Miller *et al.* teaches the use of a "water insoluble polyanionic polysaccharide (see abstract), which includes heparin (col. 3 lines 9-16) as a water insoluble composition in the form of a gel or film." *Id.* The Examiner then states it would be obvious to one of ordinary skill in the art to "modify heparin salt of Sahatjian with a water insoluble heparin composition as taught by Miller *et al.* ***for the purpose of providing a substrate that is washable in water before use*** (col. 4 lines 36-38)." *Id.* (emphasis added).

Applicants traverse the Examiner's obviousness rejection of claims 1, 2, 4, 5, 9, 10, 13, 15, 16, 18-20, 22 and 23 on the basis that the Examiner's purported reason for modifying the Sahatjian device with the adhesion prevention compositions of Miller *et al.* is purely conclusory and illogical at best, and does not support a finding that one of ordinary skill in the art would have combined the prior art elements in the manner claimed.[i]

[i] Applicants call the Examiner's attention to the *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.* (Fed. Reg., Vol. 72, No. 195, pp. 57526-57535) that took effect on October 10, 2007. It appears that the Examiner is trying to use Rationale B, *i.e.*, substituting one known element for another to obtain predictable results; however, Miller *et al.* does not provide the missing element or a predictable result. The water insoluble compositions disclosed in Miller *et al.* would not be applicable to a water insoluble salt of a therapeutic material that are to be dispersed within a porous material as recited in claim 1, as Applicants contend that the Miller *et al.* compositions are water insoluble gels or foams that stand alone *in vivo* and may include a therapeutic material therein (see col. 3, line 66- col. 4, line 10) but could not be predictably loaded within a porous matrix on a stent as a therapeutic material.

As an initial matter, Miller *et al.* teaches a method of making a water insoluble biocompatible composition in the form of a film, foam, gel or other form suitable for application by syringe for use as an adhesion prevention composition after surgery to prevent post-operative adhesion between body tissues. The composition **prevents tissue contact** for a long enough period so that when it finally disperses and the tissues do come into contact, the tissues no longer have a tendency to adhere. *See* Miller *et al.* col. 1, lines 33-42; col. 3, lines 63-66; col. 4, lines 45-49; and col. 15, lines 40-47. Other uses of the insoluble materials made according to the teachings of Miller *et al.* are as surface pacification agents, sealing agents between tubular bodies, a biocompatible fiber, a sclerosing agent and an artificial extracellular matrix material for tissue replacement. *See* Miller *et al.* col. 15, lines 48-59. Accordingly, Miller *et al.* does not teach or suggest using its water insoluble compositions as a "water insoluble salt of a therapeutic material" for dispersing in a porous material as claimed in independent claim 1.

Further, although Miller *et al.* does mention that because its "gels and films are water insoluble, they can be thoroughly washed with water before use **to remove unreacted substances**" (col. 4, lines 36-38 (emphasis added)), Applicants assert that this "benefit" would not lead one of ordinary skill in the art to modify Sahatjian to use a "water insoluble salt of a therapeutic material" within a porous material to create a drug eluting stent as claimed in independent claim 1. In fact, Applicants submit that it would be undesirable for a clinician to "wash" a drug eluting stent in water before use, as medical devices, such as a delivery catheter loaded with a drug eluting stent, are packaged to be sterile. Washing in water to remove unreacted substances may be relevant for a gel or foam composition according to Miller *et al.* because unreacted polyanionic polysaccharides would not be water insoluble, which would leave them free to react/dissolve *in vivo*. *See* Miller *et al.* col. 2, lines 51-56; col. 3, lines 42-58. However, washability of a drug eluting stent seems a rather tenuous reason for modifying Sahatjian in view of the Examiner's alleged teaching of a water insoluble salt according to Miller *et al.*

Applicants also reiterate that Sahatjian discloses a heparin salt ***solution*** that is captured within a hydrogel polymeric coating to be freely released upon compression of the polymeric coating with expansion of the stent. *See* Sahatjian col. 8, lines 17-30 (Example 1); *see also* col. 9, lines 39-41, 54-55 (drug in aqueous solution) and col. 10, lines 17-20 (drug solutions). Thus, even if Miller *et al.* taught a "water insoluble salt of a therapeutic material" for dispersing in a

porous material on a stent framework, the suggested modification of Sahatjian would change the principle of operation of Sahatjian because a water-insoluble salt of a therapeutic material would not provide a rapid release of a desired dosage of drug during compression of the hydrogel polymer coating of Sahatjian, as noted throughout the specification. *See, e.g.,* Sahatjian Abstract, lines 14-21; col. 1, lines 54-61; col. 1, line 68-col. 2, line 4; col. 2, lines 33-45 and 55-68; col. 3, lines 28-33; col. 4, lines 45-55 and 64-67; col. 5, lines 6-12 and 30-36; col. 6, lines 28-37; col. 8, lines 26-30; col. 9, lines 54-55; col. 10, lines 17-20. Sahatjian also discloses that for use with hydrogels according to its specification, "the drug is preferably ***water soluble***, so that the drug may be easily absorbed into the coating matrix" (col. 6, lines 28-33 (emphasis added)), and therefore teaches against using a water-insoluble salt as suggested by the Examiner.

As such, Sahatjian and Miller *et al.*, alone or in combination, do not teach or suggest a drug eluting stent having a porous material that includes "a plurality of particles of a water-insoluble salt" of a therapeutic material dispersed therein as claimed in independent claim 1. Accordingly, independent claim 1 is not anticipated by and is patentable over Sahatjian and Miller *et al.*, alone or in combination.

Claims 2, 4, 5, 9, 10, 13, 15, 16, 18-20, 22 and 23 depend from and add further features to independent claim 1 and are patentable for that reason alone. While it is not necessary to address the Examiner's rejection of the dependent claims at this time, Applicants reserve the right to support their patentability, when necessary.

35 U.S.C. §103(a) Rejections

Claims 14, 17 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sahatjian and Miller *et al.* as applied to claim 1 above and further in view of U.S. Patent No. 5,716,981 to Hunter *et al*. Claim 21 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sahatjian and Miller *et al.* as applied to claim 1 above and further in view of U.S. Patent No. 5,304,121 to Tang *et al.*

As discussed above, Sahatjian and Miller *et al.*, alone or in combination, do not teach or suggest a drug eluting stent having a porous material that includes "a plurality of particles of a water-insoluble salt" of a therapeutic material dispersed therein as claimed in independent claim 1. Further neither Hunter *et al*. nor Tang *et al*. makes up for the deficiency in the Sahatjian and Miller *et al.* combination, as neither of the references teaches or suggests a porous material

loaded with particles of a water-insoluble salt of a therapeutic material as recited in claim 1. As such, claims 14, 17, 21 and 24 that depend from and add further features to independent claim 1 are patentable over the afore-mentioned combination of references for that reason alone. While it is not necessary to address the Examiner's rejection of the dependent claims at this time, Applicants reserve the right to support their patentability, when necessary.

CONCLUSION

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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